K133344

MAR 2 8 2014

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510(K) Summary

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Product/Device Names: MINICAP Hb A1c (PN 2215), MINICAP FLEX-PIERCING (PN 1232), Hb A1c CAPILLARY Calibrators (PN 4755), Hb A1c CAPILLARY Controls (PN 4774)

Common Name: glycosylated hemoglobin

Product Regulation Name: glycosylated hemoglobin assay

The MINICAP Hb A1c type of devices/assays are classified by FDA as Class II, under Regulation No. 21 CFR 864.7470. SEBIA is seeking clearance to import the assay described above, and by this submission is notifying FDA of its intent to market these products in the United States.

Product Code	Classification	Regulation Section	Panel
LCP	II	21 CFR 864.7470 Glycosylated hemoglobin assay	Hematology (81)
JIS	II	21 CFR 862.1150 Calibrator	Chemistry (75)
JJX	Class I, Reserved	21 CFR 862.1660 Quality control material (assayed and unassayed)	Chemistry (75)

Product Nomenclature: HEMOGLOBINS A1C BY CAPILLARY ELECTROPHORESIS

Establishment Registration Number: 8023024

STANDARDS: MINICAP Hb A1c test is standardized according to NGSP and IFCC requirements/guidelines.

This submission is limited to the MINICAP Hb A1c kit (PN 2215) using the MINICAP FLEX-PIERCING instrument (PN 1232) and the performance using the Hb A1c CAPILLARY Controls (PN 4774) with the system and Hb A1c CAPILLARY Calibrators (PN 4755)

The SEBIA Hb A1c CAPILLARY Controls *(PN 4774) and* Hb A1c CAPILLARY Calibrators *(PN 4755) were FDA cleared (K122101), December 6, 2012.*

Substantial Equivalence to Predicate Devices:
For the separation and quantification of the Hb A1c glycated fraction of hemoglobin in human blood, by capillary electrophoresis in an alkaline buffer using the MINICAP Hb A1c kit with the MINICAP FLEX-PIERCING instrument.
The new device, MINICAP Hb A1c procedure using the MINICAP FLEX-PIERCING instrument, utilizes the previous cleared SEBIA Hb A1c CAPILLARY Calibrators and Hb A1c CAPILLARY Controls (K122101).

The performance of the MINICAP Hb A1c kit using the MINICAP FLEX-PIERCING instrument, Hb A1c CAPILLARY Calibrators and Hb A1c CAPILLARY Controls was compared to the predicate device, CAPILLARYS Hb A1c kit using the CAPILLARYS 2 FLEX-PIERCING instrument, the Hb A1c CAPILLARY Calibrators and the Hb A1c CAPILLARY Controls (K122101).

Both the new device (MINICAP Hb A1c kit & MINICAP FLEX-PIERCING instrument using the Hb A1c CAPILLARY Calibrators and the Hb A1c CAPILLARY Controls) and the predicate device (CAPILLARYS Hb A1c kit & CAPILLARYS 2 FLEX-PIERCING instrument using the Hb A1c CAPILLARY Calibrators and the Hb A1c CAPILLARY Controls) use capillary electrophoresis technology. The devices compared were found to be substantially equivalent in function, concept, principle, technique, use, safety and effectiveness.

The 510(K) number of the predicate device, CAPILLARYS Hb A1c using CAPILLARYS 2 FLEX-PIERCING instrument, the Hb A1c CAPILLARY Calibrators and the Hb A1c CAPILLARY Controls predicate device, was FDA cleared as K122101 on December 6, 2012.

510K Table of Predicate Devices		
Predicate Device	**510K**	**Clearance Date**
CAPILLARYS Hb A1c CAPILLARYS 2 FLEX PIERCING	K122101	December 6, 2012
Hb A1c CAPILLARY Controls	K122101	December 6, 2012
Hb A1c CAPILLARY Calibrators	K122101	December 6, 2012

DEVICE DESCRIPTION

The MINICAP FLEX-PIERCING instrument is an automated analyzer which performs a complete hemoglobin profile for the quantitative analysis of HbA1c fraction. The hemoglobins, separated in silica capillaries, are directly detected by their absorbance at 415 nm. The assay is performed on the hemolysate of whole blood samples collected in tubes containing K2EDTA or K3EDTA as anticoagulant.

Quantitative determination of hemoglobin A1c is effective in monitoring middle-term blood glucose control in diabetic individuals.

The MINICAP Hb A1c procedure performed with the MINICAP FLEX-PIERCING instrument has been certified by the National Glycohemoglobin Standardization Program (NGSP).

Electrophoresis is a well established technique routinely used in clinical laboratories for measuring components from body fluids, including HbA1c glycated fraction. The MINICAP FLEX-PIERCING instrument has been developed to provide complete automation of this testing with fast separation and good resolution. In many aspects, the methodology can be considered as an intermediary type of technique between classical zone electrophoresis and liquid chromatography.

The MINICAP FLEX-PIERCING instrument uses the principle of capillary electrophoresis in free solution. With this technique, charged molecules are separated by their electrophoretic mobility in an alkaline buffer with a specific pH. Separation also occurs according to the electrolyte pH and electroosmotic flow.

The MINICAP FLEX-PIERCING instrument has silica capillaries functioning in parallel allowing 2 simultaneous analyses for HbA1c quantification from whole blood sample. A sample dilution with hemolysing solution is prepared and injected by aspiration at the anodic end of the capillary. A high voltage protein separation is then performed and direct detection of the hemoglobins is made at the cathodic end of the capillary at 415 nm, which is the absorbance wave length specific to hemoglobins. Before each run, the capillaries are washed with a wash solution and prepared for the next analysis with buffer.

Direct detection provides accurate relative quantification of individual hemoglobin A_{1c} fraction. In addition, the high resolution of MINICAP Hb A1c procedure allows the quantification of HbA_{1c}, even in the presence of labile HbA_{1c}, carbamylated and acetylated hemoglobins, and major hemoglobin variants such as HbS, HbC, HbD, HbE and HbF and common interfering factors such as Triglycerides, Bilirubin, Ascorbic Acid, Urea, Rheumatoid factor and Glybenclamide as outline in the package insert labeling.

By using alkaline pH buffer, normal and abnormal (or variant) hemoglobins are detected in the following order, from cathode to anode: A2/C, E, S/D, F, A0, other Hb (including minor Hb A1) and then A_{1c}.

INTENDED USE

The MINICAP Hb A1c kit is designed for separation and quantification of the HbA1c glycated fraction of hemoglobin in human whole blood, by capillary electrophoresis in alkaline buffer with the MINICAP FLEX-PIERCING instrument. Measurement of hemoglobin A1c is effective in monitoring long-term glycemic control in individuals with diabetes mellitus. Results are provided in IFCC (mmol/mol) and NGSP (%Hb A1c) units.

The MINICAP Hb A1c kit is designed for Professional Use Only.

The Hb A1c CAPILLARY Controls are designed for the quality control of human glycated hemoglobin A1c quantification with SEBIA capillary electrophoresis procedures using the MINICAP HbA1c kit with the MINICAP FLEX-PIERCING automated instrument.

The Hb A1c CAPILLARY Controls are designed for Professional Use Only.

The Hb A1c CAPILLARY Calibrators are designed for the calibration and migration control of human glycated hemoglobin A1c quantification with SEBIA capillary electrophoresis procedures using the MINICAP HbA1c kit with the MINICAP FLEX-PIERCING automated instrument.

The Hb A1c CAPILLARY Calibrators are designed for Professional Use Only.

For *In Vitro* Diagnostic Use.

PRODUCT DESCRIPTION

1. MINICAP FLEX PIERCING instrument, Part Number 1232

2. Reagent Kit

The MINICAP Hb A1c kits, Hb A1c CAPILLARY Controls and Hb A1c CAPILLARY Calibrators are used with the MINICAP FLEX- PIERCING system.
The configurations of the components are summarized:

- MINICAP Hb A1c kits in Table I.
- Hb A1c CAPILLARY Calibrators in Table II.
- Hb A1c CAPILLARY Controls in Table III.
- Reagents that are required to perform the test but are sold separately in Table IV.

For additional details, see Package Inserts and instrument operators manual. Each kit, control and calibrators is supplied with a Package Insert which contains instruction for use and all the necessary information on the reagents needed to run the tests. Each Package Insert also contains information on storage conditions, shelf life and signs of deterioration of the components and the reagents sold separately.

TABLE I. REAGENTS AND MATERIALS SUPPLIED IN THE MINICAP Hb A1c KIT (PN 2215)

ITEMS	PN 2215
Buffer (ready to use)	2 vials, 250 mL each
Hemolysing solution (ready to use)	1 vial, 225 mL
Wash solution (stock solution)	1 vial, 25 mL
Reagent Cups	1 pack of 125
Filters	3 filters
Bins for used cups	4 bins
Hemolysing solution bar code labels	5 sheets of 4 labels

TABLE II. REAGENTS AND MATERIALS SUPPLIED WITH Hb A1c CAPILLARY CALIBRATORS (PN 4755)

ITEMS	PN 4755
Hb A1c CAPILLARY Calibrator 1 (green cap) Hb A1c CAPILLARY Calibrator 2 (red cap)	1 vial of each, 600µL each
Barcode label Hb A1c CAPILLARY Calibrator 1	1
Barcode label Hb A1c CAPILLARY Calibrator 2	1

TABLE III. REAGENTS AND MATERIALS SUPPLIED WITH Hb A1c CAPILLARY CONTROLS (PN 4774)

ITEMS	PN 4744
Hb A1c CAPILLARY Control 1 (white cap) Hb A1c CAPILLARY Control 2 (black cap)	1 vial of each, 600µL each
Barcode label HbA1c CAPILLARY Control 1	2
Barcode label HbA1c CAPILLARY Control 2	2
White dilution segments*	4
Grey dilution segments*	4

** Not used with the MINICAP FLEX-PIERCING instrument*

TABLE IV. REAGENTS AND MATERIALS REQUIRED BUT NOT SUPPLIED IN THE MINICAP HbA1c KIT, Hb A1c CAPILLARY CONTROLS OR Hb A1c CAPILLARY CALIBRATORS

ITEMS	PN	COMPONENTS
CAPICLEAN	2058	1 vial, 25 mL
CAPILLARYS / MINICAP Wash Solution	2052	2 vials, 75 mL
Tubes and caps for controls	9202, 9205	200 per box, 500 per box
MINICAP Reagent Cups	2280	250 per box
Lids for bins for used reagent cups	2286	12 per box
"AUTOMATIC LOW VOLUME" bar code labels	9208	20 per box
"MANUAL LOW VOLUME" bar code labels	9209	20 per box
MINICAP FLEX-PIERCING centering rings	1612	27 per box
PHORESIS software	1110	
MINICAP FLEX-PIERCING INSTRUMENT	1232	
Update HbA1c kit for MINICAP FLEX-PIERCING	1238	

LABELING

Labeling contained in this submission includes:

A. MINICAP Hb A1c operators manual
B. MINICAP Hb A1c package insert
C. Hb A1c CAPILLARY Controls package insert
D. Hb A1c CAPILLARY Calibrators package insert

and the box labels and the product labels of the MINICAP Hb A1c kit, MINICAP Hb A1c, Hb A1c CAPILLARY Controls, Hb A1c CAPILLARY Calibrators and of the reagents and materials required but not supplied.

STUDY SUMMARY

1. *Analytical performance:*

   a. *Precision/Reproducibility:*

The reproducibility studies have been performed according to CLSI Guideline "EP5-A2: Evaluation of Precision Performance of Clinical Chemistry Devices".

Reproducibility between lots and instruments
Eight (8) different blood samples were run using the MINICAP Hb A1c procedure in both capillaries of 3 different MINICAP FLEX-PIERCING instruments and with 3 lots of MINICAP Hb A1c kits. The analyzed blood samples included 3 samples with normal HbA_{1c} level (No. 1, 2 and 3), 1 sample with HbA_{1c} level close to the cut-off value (No. 4) and 4 samples with elevated HbA_{1c} level (No. 5, 6, 7 and 8). In this study, each blood sample was analyzed on both capillaries from each instrument, including 60 runs over 10 working days (at 2 different times of the day). Within each run, samples were analyzed in duplicate.
The following tables summarize the within-run and total instrument-reagent C.V. % ranges for the HbA_{1c} concentrations (in mmol/mol) and percentages.

		Within-run reproducibility		Total reproducibility	
	Mean (% HbA_{1c})	CV min (%)	CV max (%)	Total CV min (%)	Total CV max (%)
Sample No. 1	5.2	0.9	2.0	0.9	2.2
Sample No. 2	5.4	0.9	2.1	0.9	2.1
Sample No. 3	5.5	0.5	2.0	0.7	2.1
Sample No. 4	6.4	0.5	1.9	0.8	1.9
Sample No. 5	7.9	0.7	1.4	0.8	1.6
Sample No. 6	9.1	0.0	1.1	0.0	1.1
Sample No. 7	10.1	0.6	1.1	0.6	1.2
Sample No. 8	12.3	0.4	1.2	0.6	1.8
CV (%) ranges		0.0	2.1	0.0	2.2

		Within-run reproducibility		Total reproducibility	
	Mean (HbA_{1c} concentration – mmol/mol)	CV min (%)	CV max (%)	Total CV min (%)	Total CV max (%)
Sample No. 1	33	0.9	3.5	0.9	3.5
Sample No. 2	36	1.1	4.0	1.2	4.0
Sample No. 3	37	0.0	3.0	1.4	3.3
Sample No. 4	47	1.2	2.6	1.3	2.6
Sample No. 5	63	0.7	1.6	0.7	2.2
Sample No. 6	76	0.0	1.4	0.0	1.4
Sample No. 7	87	0.3	1.3	0.3	1.4
Sample No. 8	110	0.4	1.4	0.6	2.2
CV (%) ranges		0.0	4.0	0.0	4.0

Reproducibility within the same capillary and between capillaries from the same instrument
Eight (8) different blood samples were run using the MINICAP Hb A1c procedure in both capillaries of the same MINICAP FLEX-PIERCING instrument and with 1 lot of MINICAP Hb A1c kit. The analyzed blood samples included 3 samples with normal HbA_{1c} level (No. 1, 2 and 3), 1 sample with HbA_{1c} level close to the cut-off value (No. 4) and 4 samples with elevated HbA_{1c} level (No. 5, 6, 7 and 8). In this study, each blood sample was analyzed on both capillaries from the same

instrument, including 40 runs over 20 working days (at 2 different times of the day). Within each run, samples were analyzed in duplicate.
The results for HbA_{1c} concentrations (in mmol/mol) and percentages are summarized in the following tables.
For reproducibility within the same capillary, maximal CV's have been calculated for each blood sample from pooled data obtained on each capillary.

	Sample No. 1	Sample No. 2	Sample No. 3	Sample No. 4	Sample No. 5	Sample No. 6	Sample No. 7	Sample No. 8
Mean (% HbA_{1c})	5.2	5.2	5.7	6.4	7.8	9.0	10.1	11.9
Within-run reproducibility (CV %)	1.0	1.1	1.0	0.9	1.1	0.9	0.7	1.1
Within-capillary reproducibility (CV %)*	1.4	1.4	1.5	1.1	0.7	0.8	0.8	0.9
Between-run reproducibility (CV %)	0.0	0.3	0.7	0.0	0.0	0.0	0.3	0.0
Between-day reproducibility (CV %)	0.7	0.0	0.5	0.6	0.2	0.4	0.3	0.1
Total (CV %)*	1.2	1.1	1.3	1.1	1.1	1.0	0.8	1.1

	Sample No. 1	Sample No. 2	Sample No. 3	Sample No. 4	Sample No. 5	Sample No. 6	Sample No. 7	Sample No. 8
Mean (HbA_{1c} concentration – mmol/mol)	33	34	38	46	62	75	87	106
Within-run reproducibility (CV %)	1.7	1.9	1.7	1.1	0.8	1.2	0.8	1.2
Within-capillary reproducibility (CV %)	2.5	2.8	2.4	1.3	0.8	1.2	1.0	0.9
Between-run reproducibility (CV %)	0.0	1.4	0.3	0.5	0.0	0.0	0.4	0.0
Between-day reproducibility (CV %)	1.3	0.0	0.6	0.5	0.0	0.6	0.3	0.2
Total (CV %)	2.2	2.3	1.8	1.3	0.8	1.3	1.0	1.2

b. Linearity/assay reportable range:

The linearity of the MINICAP HbA1c procedure was evaluated based on CLSI EP6-A guideline "Evaluation of the Linearity Quantitative Measurement Procedures: A Statistical Approach". Two blood samples, including a normal sample with HbA1c concentration at 4.8% (29 mmol/mol) and an elevated HbA1c level sample with HbA1c concentration at 13.8% (127 mmol/mol) were mixed within different proportions and the dilutions were electrophoresed with the MINICAP HbA1c assay kit using the MINICAP FLEX-PIERCING instrument. Samples were analyzed in duplicate.

A polynomial regression analysis was performed, it allows to conclude on the linearity of MINICAP Hb A1c procedure performed with the MINICAP FLEX-PIERCING instrument for HbA1c fraction within the entire range studied.

HbA1c (%)
The 1st order linear regression generated is:
$Y=0.08982x+4.764$, $r^2=0.998$, $r=0.999$
The linearity range is 4.8 – 13.8% HbA1c

HbA1c (mmol/mol)
The 1st order linear regression generated is:
$Y=0.9855x+28.41$, $r^2=0.999$, $r=0.999$
The linearity range is 29 – 127 mmol/mol HbA1c
In addition, 3 different characteristic blood samples, including a normal sample with HbA1c concentration at 5.0 % HbA1c (31 mmol/mol), a sample with HbA1c level close to the cut-off value at 6.3 % HbA1c (46 mmol/mol) and an elevated HbA1c level sample with HbA1c concentration at

9.3 % HbA1c (79 mmol/mol), were all serially diluted in hemolysing solution and electrophoresed with the MINICAP Hb A1c procedure. The tests were determined to be linear within the entire ranges studied from 2.5 to 31.1 g/dL total hemoglobin and HbA1c fraction concentration and percentage were not affected by the hemoglobin concentration of the samples.

c. Detection limit:

The Limit of Blank (LoB) and Limit of Detection (LoD) were determined by assaying a five zero samples (blank) and six low HbA1c samples according to CLSI guideline EP17-A . The results are as follows:
LoB= 0.3%, LoD = 1.1%

The claimed measuring range, 4.8- 13.8% (29 – 127 mmol/mol), is based on linearity.

d. Analytical specificity:

The interference studies have been performed according to the CLSI Guideline "EP7-A2: Interference Testing in Clinical Chemistry".

i) Studies were performed to assess common or known substances that could interfere with the MINICAP HbA1c assay kit. The interfering substances were evaluated in whole blood samples that contained four different concentrations of A1c (~5.0%, ~6.5%, ~8.8% and ~11.9%). Samples containing various concentrations of potential interferents were tested and the results compared to those obtained from control samples containing no potential interfering substances. The definition of non-significant interference is ≤ 0.3% HbA1c between the tested and the control samples.
The results are as follows:

Potential interfering substance	Concentration at which no significant interference (≤0.3%) was observed
Triglycerides	3.07 g/dL (35.1 mM)
Bilirubin	25.8 mg/dL (442 µM)
Ascorbic acid	60 mg/dL (3.41 mM)
Urea	291 mg/dL (48.5 mM)
Rheumatoid factor	2178 IU/mL
Glybenclamide	3 mg/dL

ii) To study interference from Carbamlyated hemoglobin, four whole blood patient samples with A1c concentrations at ~5.7%, ~6.9%, ~8.9% and ~12.4% were split into two aliquots. One aliquot, at each A1c level, was spiked with 8.11 mg/dL (1 mmol/L) of Potassium Cyanate and incubated for 3 hours at 37°C. Another aliquot, at each A1c level, was incubated for 3 hours at 37°C. Samples were then analyzed on the MINICAP FLEX-PIERCING instrument using the MINICAP HbA1c assay kit, Samples were analyzed in triplicate. The definition of non-significant interference is ≤ 0.3 HbA1c% between the tested and the control samples.

To conclude Carbamylated hemoglobin (≤ 8.7 %) does not interfere with this assay.

iii) To study interference from Labile HbA1c, four whole blood patient samples with A1c concentrations at ~4.7%, ~6.8%, ~8.8% and ~12.7% were split into two aliquots. One aliquot, at each A1c level, was spiked with 1800 mg/dL (0.5 mol/L) of glucose and incubated for 3 hours at 37°C. Another aliquot, at each A1c level, was incubated for 3 hours at 37°C. Samples were then analyzed on the MINICAP FLEX-PIERCING instrument using the MINICAP HbA1c assay kit, Samples were analyzed in triplicate. The definition of non-significant interference is ≤ 0.3 HbA1c% between the tested and the control samples.

To conclude Labile Hb A1c (≤ 14.8 %) does not interfere with this assay.

iv) To study interference from Labile HbA1c, four whole blood patient samples with A1c concentrations at ~5.2%, ~6.6%, ~9.4% and ~11.7% were split into two aliquots. One aliquot, at each A1c level, was spiked with 180 mg/dL (10 mmol/L) of acetylsalicylic and incubated for 4 hours at 37°C. Another aliquot, at each A1c level, was incubated for 4 hours at 37°C. Samples were then analyzed on the MINICAP FLEX-PIERCING instrument using the MINICAP HbA1c assay kit, Samples were analyzed in triplicate. The definition of non-significant interference is ≤ 0.3 HbA1c% between the tested and the control samples.

To conclude Acetylated hemoglobin (≤ 3.0 %) does not interfere with this assay.

v) A hemoglobin variant interference study was carried out using samples known to contain Hemoglobin variants S, E, D and C. These variant samples were tested on the MINICAP FLEX-PIERCING instrument using the MINICAP HbA1c assay kit. The definition of non-significant interference is ±10% difference between the candidate method and a NGSP reference method (performed in a NGSP laboratory).

The testing results show there is no significant interference for HbS (≤ 40.5%), HbE (≤ 24.7%), HbD (≤ 41.0%) and HbC (≤ 37.0%).

vi) An additional variant interference study was carried out to study the variant interference from Hemoglobin F. 16 whole blood samples with HbA1c concentrations of ~5.3% and ~11.6% contained various concentrations of HbF (2.3 to 19.7%) were tested on the MINICAP FLEX-PIERCING instrument using the MINICAP HbA1c assay kit. The definition of non-significant interference is ±10% difference between the candidate method and a NGSP reference method (performed in a NGSP laboratory).

The testing results show there is no significant interference for HbF ≤ 19.7%.

2. *Comparison studies:*
   a. Method comparison with predicate device:

The correlation studies have been performed according to CLSI Guideline "EP9-A2: Method Comparison and Bias Estimation Using Patient Samples".

Internal Study :
101 whole blood samples with HbA1c ranging from 4.8% (29 mmol/mol) to 13.3% (122 mmol/mol) were analyzed in singlicate using the MINICAP HbA1c assay kit on the MINICAP FLEX-PIERCING instrument (candidate device) and on the CAPILLARYS Hb A1c assay on the CAPILLARYS 2 FLEX-PIERCING instrument. The linear regression correlation was calculated as follows:

HbA_{1c}	Correlation coefficient	y-Intercept	Slope	Range of values MINICAP Hb A1c
Percentage (%)	0.998	0.165	0.982	4.8 – 13.3
Concentration (mmol/mol)	0.998	1.262	0.985	29 – 122

External study No.1
126 whole blood samples with HbA1c ranging from 4.8% (29 mmol/mol) to 13.6% (125 mmol/mol) were analyzed in singlicate using the MINICAP HbA1c assay kit on the MINICAP FLEX-PIERCING

instrument (candidate device) and on the CAPILLARYS Hb A1c assay on the CAPILLARYS 2 FLEX-PIERCING instrument. The linear regression correlation was calculated as follows:

HbA_{1c}	Correlation coefficient	y-Intercept	Slope	Range of values MINICAP Hb A1c
Percentage (%)	0.998	- 0.032	0.997	4.8 – 13.6
Concentration (mmol/mol)	0.998	- 0.396	0.996	29 – 125

External study No. 2

140 whole blood samples with HbA1c ranging from 4.8% (29 mmol/mol) to 13.1% (119 mmol/mol) were analyzed in singlicate using the MINICAP HbA1c assay kit on the MINICAP FLEX-PIERCING instrument (candidate device) and on the CAPILLARYS Hb A1c assay on the CAPILLARYS 2 FLEX-PIERCING instrument. The linear regression correlation was calculated as follows:

HbA_{1c}	Correlation coefficient	y-Intercept	Slope	Range of values MINICAP Hb A1c
Percentage (%)	0.998	- 0.057	1.019	4.8 – 13.1
Concentration (mmol/mol)	0.998	- 0.316	1.023	29 – 119

b. Matrix comparison:

A total of 41 random matched sample pairs (K2 EDTA and K3 EDTA) were tested on the MINICAP FLEX-PIERCING instrument using the MINICAP HbA1c assay kit. The linear regression is presented in the table below:

Fraction	Number of samples	Correlation coefficient	y-intercept	Slope	Range of HbA1c fractions (test)
HbA1c (%)	41	0,999	0,039	0,998	4,9 - 13,3
HbA1c (mmol/mol)	41	0,999	0,091	1,001	30 - 122

SUBSTANTIAL EQUIVALENCE

The performance and comparative studies of the MINICAP Hb A1c test with the MINICAP FLEX-PIERCING instrument were performed using SEBIA's commercially available materials and standard procedures.

In the comparative studies, commercially available materials and standard procedures were used with the predicate device: CAPILLARYS Hb A1c using the CAPILLARYS 2 FLEX-PIERCING instrument (K122101).

Both the new device MINICAP Hb A1c with the MINICAP FLEX-PIERCING and the predicate method, CAPILLARYS Hb A1c with the CAPILLARYS 2 FLEX-PIERCING instrument use the same technology of capillary electrophoresis of blood samples for Hb A1c analysis. The MINICAP HbA1c kit using the MINICAP FLEX-PIERCING instrument and the predicate device the CAPILLARYS Hb A1c kit used with the CAPILLARYS 2 FLEX-PIERCING instrument utilize EDTA collection tubes of (K2 and K3).

The SEBIA MINICAP Hb A1c procedure, performed with the MINICAP FLEX-PIERCING system was found to be substantially equivalent in function, use, safety, effectiveness and the performance to predicate devices described above.
The following tables A, B, C and D present the similarities and the differences.

Table A : SEBIA MINICAP Hb A1c kit used with the MINICAP FLEX PIERCING instrument as compared to the predicate CAPILLARYS Hb A1c kit used with the CAPILLARYS 2 FLEX-PIERCING instrument

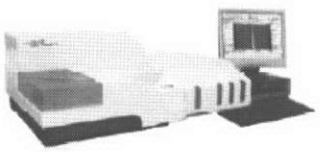
Table B: SEBIA Hb A1c CAPILLARY Calibrators used with the MINICAP Hb A1C kit and MINICAP FLEX-PIERCING Instrument to the predicate CAPILLARYS Hb A1c kit used with the CAPILLARYS 2 FLEX-PIERCING instrument.

Table C: SEBIA Hb A1c CAPILLARY Controls used with the MINICAP Hb A1c kit and MINICAP FLEX-PIERCING instrument as compared to the predicate devices CAPILLARYS Hb A1c kit used with the CAPILLARYS 2 FLEX-PIERCING instrument.

Table D: SEBIA MINICAP FLEX-PIERCING Instrument to the predicate the CAPILLARYS 2 FLEX-PIERCING instrument.

Table A

SEBIA MINICAP Hb A1c kit used with the MINICAP FLEX PIERCING instrument as compared to the predicate CAPILLARYS Hb A1c kit used with the CAPILLARYS 2 FLEX-PIERCING instrument.

	SEBIA CAPILLARYS Hb A1c technique with CAPILLARYS 2 FLEX-PIERCING instrument	**SEBIA MINICAP Hb A1c technique with MINICAP FLEX-PIERCING instrument**
Intended Use	The CAPILLARYS Hb A1c kit is designed for separation and quantification of the HbA1c glycated fraction of hemoglobin in human blood, by capillary electrophoresis in alkaline buffer (pH 9.4) with the CAPILLARYS 2 FLEX-PIERCING instrument. Measurement of hemoglobin A1c is effective in monitoring long-term glycemic control in individuals with diabetes mellitus. The CAPILLARYS Hb A1c kit is designed for Professional Use Only. For *In Vitro* Diagnostic Use.	The MINICAP Hb A1c kit is designed for separation and quantification of the HbA1c glycated fraction of hemoglobin in human blood, by capillary electrophoresis in alkaline buffer (pH 9.4) with the MINICAP FLEX-PIERCING instrument. Measurement of hemoglobin A1c is effective in monitoring long-term glycemic control in individuals with diabetes mellitus. The MINICAP Hb A1c kit is designed for Professional Use Only. For *In Vitro* Diagnostic Use.
Separation system	Free solution capillary electrophoresis (FSCE): protein separation in an alkaline buffer (pH 9.4) according to their charge, to the electrolyte pH and electroosmotic flow. Fast separation and good resolution. Electrophoregrams show separated fractions according to their charge.	Same
Instrument	SEBIA CAPILLARYS 2 FLEX-PIERCING instrument, PN 1227	SEBIA MINICAP FLEX-PIERCING instrument, PN 1232
Picture		
Interface	PC interface	Same
Absorbance wave length	415 nm	Same
Software	SEBIA PHORESIS™ software	Same
Number of separation units	8 parallel capillaries	2 parallel capillaries
Calibration	Yes	Yes
Sample type	Whole blood in capped tube	Same
Samples identification	Yes (Bar code reading on both sample racks and tubes)	Yes (Bar code reading on sample tubes)
Hemolysis	Performed automatically by the instrument	Same
Introduction of the samples into the automatic system	Continuous loading using sample racks	Continuous loading on the rotating sampler
Analysis throughput	40 analyses / hour	7.6 analyses / hour
Collection tubes	Tubes with K2EDTA or K3EDTA anticoagulant	Same

	SEBIA CAPILLARYS Hb A1c technique with CAPILLARYS 2 FLEX-PIERCING instrument	SEBIA MINICAP Hb A1c technique with MINICAP FLEX-PIERCING instrument
Reagent	CAPILLARYS Hb A1c Kit (PN 2015) : Buffer Hemolyzing solution Wash solution Dilution segments Filters CAPILLARY Hb A1c CALIBRATORS (PN 4755) : CAPILLARY Hb A1c Calibrator 1 CAPILLARY Hb A1c Calibrator 2 CAPILLARY Hb A1c CONTROLS (PN 4774) : CAPILLARY Hb A1c Control 1 CAPILLARY Hb A1c Control 2	MINICAP Hb A1c Kit (PN 2215) : Buffer Hemolyzing solution Wash solution Reagent cups Filters Bins for used cups Hemolysing solution bar code labels CAPILLARY Hb A1c CALIBRATORS (PN 4755) : CAPILLARY Hb A1c Calibrator 1 CAPILLARY Hb A1c Calibrator 2 CAPILLARY Hb A1c CONTROLS (PN 4774) : CAPILLARY Hb A1c Control 1 CAPILLARY Hb A1c Control 2
Standardization	NGSP IFCC	NGSP IFCC

Table B

SEBIA Hb A1c CAPILLARY Calibrators used with the MINICAP Hb A1c kit and MINICAP FLEX-PIERCING Instrument to the predicate CAPILLARYS Hb A1c kit used with the CAPILLARYS 2 FLEX-PIERCING instrument.

	SEBIA HbA1c CAPILLARY CALIBRATORS K122101	**SEBIA HbA1c CAPILLARY CALIBRATORS**
Intended Use	The Hb A1c CAPILLARY Calibrators are designed for the calibration and migration control of human glycated hemoglobin A1c quantification with SEBIA CAPILLARYS Hb A1c electrophoresis procedure performed with the CAPILLARYS 2 FLEX-PIERCING automated instrument for capillary electrophoresis. The Hb A1c CAPILLARY Calibrators are designed for professional Use Only. For *In Vitro* Diagnostic Use.	The Hb A1c CAPILLARY Calibrators are designed for the calibration and migration control of human glycated hemoglobin A1c quantification with SEBIA capillary electrophoresis procedures : - CAPILLARYS Hb A1c performed with the CAPILLARYS 2 FLEX-PIERCING automated instrument and, - MINICAP Hb A1c performed with the MINICAP FLEX-PIERCING automated instrument. The Hb A1c CAPILLARY Calibrators are designed for Professional Use Only. For *In Vitro* Diagnostic Use
Product Number	4755	4755
Format	2 levels 1 vial (0.6 mL) per level	Same
Preparation	Reconstitute each lyophilized calibrator vial with 0.6 mL of distilled or deionized water.	Same
Storage temperature	Before reconstitution, the lyophilized calibrators must be stored between - 30 °C and - 18 °C. They are stable until the expiration date indicated on the vial labels.	Same
In use storage	After reconstitution, store the calibrators at 2 - 8 °C in a closed conical tube for control blood and use them within the day (for 8 hours maximum). After use, they must be stored without any delay between - 18 °C and - 22 °C due to the risk of microbial contamination and denaturation. They are stable for 6 months maximum between - 18 °C and - 22 °C. Do not freeze and thaw the reconstituted calibrators more than 3 times.	CAPILLARYS 2 FLEX-PIERCING : After reconstitution, store the calibrators at 2 - 8 °C in a closed conical tube for control blood and use them within the day (for 8 hours maximum). After use, they must be stored without any delay between - 18 °C and - 22 °C due to the risk of microbial contamination and denaturation. They are stable for 22 months maximum between - 18 °C and - 22 °C. Do not freeze and thaw the reconstituted calibrators more than 3 times. MINICAP FLEX-PIERCING : After reconstitution, prepare 2 aliquots with equivalent volumes (≈ 0.4 mL) of the whole amount of each calibrator in conical tubes for control blood, for use and / or storage. Store the aliquoted calibrators at 2 – 8 °C in a closed conical tube for control blood and use them within the day (for 8 hours maximum). After use, they must be stored without any delay between – 18 °C and – 22 °C due to the risk of microbial contamination and denaturation. They are stable for 22 months maximum between – 18 °C and – 22 °C. Do not freeze and thaw the reconstituted calibrators more than 5 times.
Traceability	The assigned values are traceable to IFCC.	Same
Instrument	SEBIA CAPILLARYS 2 FLEX-PIERCING	SEBIA CAPILLARYS 2 FLEX-PIERCING SEBIA MINICAP FLEX-PIERCING

Table C

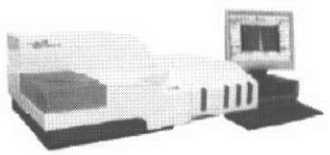
SEBIA Hb A1c CAPILLARY Controls used with the MINICAP Hb A1c kit and MINICAP FLEX-PIERCING instrument as compared to the predicate devices CAPILLARYS Hb A1c kit used with the CAPILLARYS 2 FLEX-PIERCING instrument.

	SEBIA HbA1c CAPILLARY CONTROLS K122101	**SEBIA HbA1c CAPILLARY CONTROLS**
Intended Use	The Hb A1c CAPILLARY Controls are designed for the quality control of human glycated hemoglobin A1c quantification with CAPILLARYS Hb A1c electrophoresis procedure performed with the CAPILLARYS 2 FLEX-PIERCING automated instrument for capillary electrophoresis. They should be used like any biological samples. The values obtained must fall within the range determined for each batch. For *In Vitro* Diagnostic Use.	The Hb A1c CAPILLARY Controls are designed for the quality control of human glycated hemoglobin A1c quantification with SEBIA capillary electrophoresis procedures : - CAPILLARYS Hb A1c performed with the CAPILLARYS 2 FLEX-PIERCING automated instrument and, - MINICAP Hb A1c performed with the MINICAP FLEX-PIERCING automated instrument. The Hb A1c CAPILLARY Controls are designed for Professional Use Only. For *In Vitro* Diagnostic Use.
Product Number	4774	4774
Format	2 levels 1 vial (0.6 mL) per level	Same
Preparation	Reconstitute each lyophilized control vial with 0.6 mL of distilled or deionized water.	Same
Storage temperature	Before reconstitution, the lyophilized controls must be stored refrigerated (2 to 8 °C). They are stable until the expiration date indicated on the vial labels.	Same
In use storage	After reconstitution, store the controls at 2 - 8 °C in a closed conical tube for control blood and use them within the day (for 8 hours maximum). After use, they must be stored without any delay between - 18 °C and - 22 °C due to the risk of microbial contamination and denaturation. They are stable for 6 months maximum between - 18 °C and - 22 °C. Do not freeze and thaw the reconstituted controls more than 30 times. After hemolysis with the CAPILLARYS 2 FLEX-PIERCING instrument, store the dilution segments with controls at 2 - 8 °C and use them within the day (for 8 hours maximum). They may be stored, without any delay, between - 18 °C and - 22 °C for 1 month maximum. Do not freeze and thaw a dilution segment with hemolyzed control more than three times.	CAPILLARYS 2 FLEX-PIERCING : After reconstitution, store the controls at 2 - 8 °C in a closed conical tube for control blood and use them within the day (for 8 hours maximum). After use, they must be stored without any delay between - 18 °C and - 22 °C due to the risk of microbial contamination and denaturation. They are stable for 6 months maximum between - 18 °C and - 22 °C. Do not freeze and thaw the reconstituted controls more than 30 times. After hemolysis with the CAPILLARYS 2 FLEX-PIERCING instrument, store the dilution segments with controls at 2 - 8 °C and use them within the day (for 8 hours maximum). They may be stored, without any delay, between - 18 °C and - 22 °C for 1 month maximum. Do not freeze and thaw a dilution segment with hemolyzed control more than three times. MINICAP FLEX-PIERCING : After reconstitution, store the controls at 2 - 8 °C in a closed conical tube for control blood and use them within the day (for 8 hours maximum). After use, they must be stored without any delay between - 18 °C and - 22 °C due to the risk of microbial contamination and denaturation. They are stable for 6 months maximum between - 18 °C and - 22 °C. Do not freeze and thaw the reconstituted controls more than 30 times.

	SEBIA HbA1c CAPILLARY CONTROLS K122101	**SEBIA HbA1c CAPILLARY CONTROLS**
Instrument	SEBIA CAPILLARYS 2 FLEX-PIERCING	SEBIA CAPILLARYS 2 FLEX-PIERCING SEBIA MINICAP FLEX-PIERCING

TABLE D

SEBIA MINICAP FLEX-PIERCING Instrument to the predicate the CAPILLARYS 2 FLEX-PIERCING instrument.

	SEBIA CAPILLARYS 2 FLEX-PIERCING instrument	**SEBIA MINICAP FLEX-PIERCING instrument**
Intended Use	The CAPILLARYS 2 FLEX-PIERCING instrument is designed and intended for the human protein and hemoglobin separation by capillary electrophoresis on 8 parallel capillaries. The analysis is performed using uncapped tubes or capped tubes with a cap piercing function according to the procedure. The CAPILLARYS 2 FLEX-PIERCING instrument is intended to be used with the SEBIA CAPILLARYS reagent kits. The CAPILLARYS 2 FLEX-PIERCING instrument is designed for Professional Use Only. For *In Vitro* Use.	The MINICAP FLEX-PIERCING instrument is designed and intended for the human protein and hemoglobin separation by capillary electrophoresis on 2 parallel capillaries. The analysis is performed using uncapped tubes or capped tubes with a cap piercing function according to the procedure. The MINICAP FLEX-PIERCING instrument is intended to be used with the SEBIA MINICAP reagent kits. The MINICAP FLEX-PIERCING instrument is designed for Professional Use Only. For *In Vitro* Use.
Separation system	Free solution capillary electrophoresis (FSCE): protein separation in an alkaline buffer according to their charge, to the electrolyte pH and electroosmotic flow. Fast separation and good resolution. Electrophoregrams show separated fractions according to their charge.	Same
Product Number	PN 1227	PN 1232
Picture		
Interface	PC interface	Same
Detection system	Deuterium lamp	Deuterium lamp and LED
Software	SEBIA PHORESIS™ software	Same
Number of separation units	8 parallel capillaries	2 parallel capillaries
Samples tubes	uncapped tubes or capped tubes depending on the procedure	Same
Samples identification	Yes (Bar code reading on both sample racks and tubes)	Yes (Bar code reading on sample tubes)
Introduction of the samples into the automatic system	Continuous loading using sample racks	Continuous loading on the rotating sampler
Dimensions	L. 95 cm x H. 39 cm x D. 63 cm	L. 44 cm x H. 41.5 cm x D. 58 cm
Weight	50 kg	32 kg

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

SEBIA
C/O KAREN ANDERSON
DIRECTOR OF TECHNICAL AND QUALITY ASSURANCE
1705 CORPORATE DRIVE SUITE 400
NORCROSS GA 30093

March 28, 2014

Re: K133344
Trade/Device Name: Minicap HbA1c kit, Hb A1c Capillary Controls, Hb A1c Capillary Calibrators
Regulation Number: 21 CFR 864.7470
Regulation Name: Glycosylated hemoglobin assay
Regulatory Class: II
Product Code: LCP, JIS, JJX
Dated: February 18, 2014
Received: February 20, 2014

Dear Ms. Anderson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ruth A. Chesler -S

for
Courtney H. Lias
Director, Division of Chemistry and Toxicology
Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K133344

Device Name
Hb A1c CAPILLARY Calibrators using the MINICAP FLEX-PIERCING instrument

Indications for Use *(Describe)*
The Hb A1c CAPILLARY Calibrators are designed for the calibration and migration control of human glycated hemoglobin A1c quantification with SEBIA capillary electrophoresis procedures using the MINICAP Hb A1c kit with the MINICAP FLEX-PIERCING automated instrument.

The Hb A1c CAPILLARY Calibrators are designed for Professional Use Only.
For In Vitro Diagnostic Use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Katherine Serrano -S

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Paperwork Reduction Act (PRA) Staff
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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K133344

Device Name
Hb A1c CAPILLARY Controls using the MINICAP FLEX-PIERCING instrument

Indications for Use *(Describe)*
The Hb A1c CAPILLARY Controls are designed for the quality control of human glycated hemoglobin A1c quantification with SEBIA capillary electrophoresis procedures using the MINICAP Hb A1c kit with the MINICAP FLEX-PIERCING automated instrument.

The Hb A1c CAPILLARY Controls are designed for Professional Use Only.
For In Vitro Diagnostic Use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K133344

Device Name
MINICAP Hb A1c kit

Indications for Use *(Describe)*
The MINICAP Hb A1c kit is designed for separation and quantification of the HbA1c glycated fraction of hemoglobin in human whole blood, by capillary electrophoresis in alkaline buffer with the MINICAP FLEX-PIERCING instrument. Measurement of hemoglobin A1c is effective in monitoring long-term glycemic control in individuals with diabetes mellitus. Results are provided in IFCC (mmol/mol) and NGSP (%Hb A1c) units.

The MINICAP Hb A1c kit is designed for Professional Use Only.
For In Vitro Use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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